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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/302,896 04/30/99 CHANCELLOR

M 2710-4007-US

EXAMINER

HM12/0509

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345 PARK AVENUE  
NEW YORK NY 10154

KALISHAI, S	
ART UNIT	PAPER NUMBER

1633

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/302,896

Applicant(s)

CHANCELLOR ET AL.

Examiner

Sumesh Kaushal

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 April 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-118b are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 43-48, 63-68, 81, 83-91, 92-101, 102, 104, 106-116 drawn to a method of repairing genitourinary tract tissue wherein the dysfunction is Urinary stress incontinence is related to Sphincter defects, classified in class 514, subclass 44.
- II. Claims 1-14, 43-48, 63-68, 82-91, 92-101, 103, 105-114, 117 drawn to a method of repairing genitourinary tract tissue wherein the dysfunction is Urinary stress incontinence is related to Urethral defects, classified in class 514, subclass 44.
- III. Claims 1-14, 43-48, 63-68, 82-91, 92-101, 103-117 drawn to a method of repairing genitourinary tract tissue wherein the dysfunction is Urinary stress incontinence is related to Bladder dysfunction, classified in class 514, subclass 44.
- IV. Claims 1-14, 49-55, 63-68, 81, 83-91, 92-101, 102, 104, 106-116 drawn to a method of repairing genitourinary tract tissue wherein the dysfunction is Erectile dysfunction, classified in class 514, subclass 44.
- V. Claims 15-26, 56-62, 63-68, 76-80, 118 drawn to a method of repairing Musculoskeletal tissue, classified in class 514, subclass 44.
- VI. Claim 27-42, 56-62, 63-68, 69-75, drawn to a method of repairing Bone defect, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to method of repairing genitourinary tract tissue to treat urinary stress incontinence caused by following defects: i) sphincter defects, ii) urethral defects and iii) bladder dysfunction. These defects have different sites in the urinary tract and have different modes of operation to regulate urination. For example, the sphincter muscle open and control bladder neck, Urethral muscle regulates urodynamic and the bladder muscles contract to empty bladder during urination. Therefore, these inventions are distinct and are of separate uses.

Inventions of Groups I-III are distinct from invention of Groups IV, V and VI. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to a method of repairing i) Urinary tract dysfunction, ii) Erectile dysfunction, iii) Musculoskeletal tissue defects and iv) Bone defects. These methods have different site of action in different organs in vivo that have different modes of operation. For example, erectile dysfunction has different modes of operation, functions, and effects as compared to urinary tract function. Moreover the erectile function is only limited to male population. Furthermore, musculoskeletal tissue defects are limited to skeletal muscles whereas the bone defects are limited to bones only. In addition the defects to be treated in genitourinary system are distinct from musculoskeletal tissue or and/or bones. Thus, these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and the search required for Group I-III is not required for Group IV-VI, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Deborah Clark can be reached on (703) 305-4051. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Tracey Johnson, whose telephone number is (703) 308-0377. If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.



S. Kaushal,  
PATENT EXAMINER  
AU 1633